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CLAIMS

1. Particles suitable for delivery from a particle-mediated delivery device, which particles are obtainable by precipitating a nucleic acid on inert metal carrier particles in the presence of a nucleic acid condensing agent and a metal ion
5 chelating agent.
2. Particles according to claim 1 wherein the inert metal carrier particles are selected from the group consisting of gold, tungsten, platinum and iridium particles.
3. Particles according to claim 2 wherein the inert metal carrier particles
10 are gold particles having a diameter from about 1 to 3 μ m.
4. Particles according to any one of the preceding claims wherein the nucleic acid encodes an antigen.
5. Particles according to claim 4 wherein the antigen is selected from the group consisting of viral antigens, bacterial antigens and fungal antigens.
- 15 6. Particles according to any one of claims 1 to 3 wherein the nucleic acid encodes a therapeutic polypeptide.
7. Particles according to any one of the preceding claims wherein the nucleic acid is DNA.
8. Particles according to any one of the preceding claims wherein the
20 nucleic acid condensing agent is a cationic polymer.
9. Particles according to claim 8 wherein the nucleic acid condensing agent is a polyamine.
10. Particles according to claim 9 wherein the polyamine is selected from the group consisting of protamines, spermidine, spermine, putrescine, and
25 physiologically acceptable salts thereof.
11. Particles according to claim 9 wherein the polyamine is a polyarginine or a polylysine.
12. Particles according to claim 11 wherein the polyarginine is (Arg)₄ or (Arg)₆.

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13. Particles according to any one of the preceding claims wherein the metal ion chelating agent is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA) diethylenetriamine penta-acetic acid (DTPA), nitrilotriacetic acid (NTA), inositol hexaphosphate, tripolyphosphate, polyphosphoric acid, sodium succinate, potassium succinate, lithium succinate, sodium malate, potassium malate, lithium malate, desferal and ethylenediamine-di (o-hydroxy-phenylacetic) acid (EDDHA).

14. Particles according to any one of the preceding claims wherein precipitation is carried out in the presence of one or more disaccharide and/or trisaccharide sugars.

15. Particles according to claim 14 wherein the one or more sugars is selected from the group consisting of trehalose, sucrose, lactose and raffinose.

16. Particles according to claim 15 wherein the one or more sugars is a blend of sucrose and raffinose.

17. Particles according to any one of the preceding claims wherein precipitation is carried out in the presence of one or more salts.

18. Particles according to claim 17 wherein the one or more salts is selected from the group consisting of potassium acetate, calcium chloride, lithium chloride, sodium acetate, magnesium nitrate, sodium citrate, sodium phosphate and magnesium chloride.

19. Particles according to any one of the preceding claims wherein the resultant particles are contacted with an antioxidant.

20. Particles according to claim 19 wherein the antioxidant is selected from the group consisting of ethanol, vitamin A, vitamin C and vitamin E.

21. Particles according to claim 1 which have been obtained by precipitating DNA on gold carrier particles in the presence of a polyarginine, EDTA and sucrose.

22. A dosage receptacle for a particle-mediated delivery device, the receptacle containing particles which are obtainable by precipitating a nucleic acid on

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inert metal carrier particles in the presence of a nucleic acid condensing agent and a metal ion chelating agent.

23. A particle mediated delivery device loaded with particles which are obtainable by precipitating a nucleic acid on inert metal carrier particles in the
5 presence of a nucleic acid condensing agent and a metal ion chelating agent.

24. A particle mediated delivery device according to claim 23 which is a needleless syringe.

25. A process for the preparation of particles suitable for delivery from a particle-mediated delivery device, comprising the steps of:

10 (i) precipitating a nucleic acid on inert metal carrier particles in the presence of a nucleic acid condensing agent and a metal ion chelating agent; and
(ii) collecting the resultant particles.

26. A process according to claim 25 wherein, in step (i) the nucleic acid condensing agent is added to a mixture comprising the inert metal carrier particles
15 and the nucleic acid.

27. A process according to claim 25 or 26 wherein the inert metal carrier particles are selected from the group consisting of gold, tungsten, platinum and iridium particles.

28. A process according to claim 27 wherein the inert metal carrier
20 particles are gold particles having a diameter from about 1 to 3 μ m.

29. A process according to any one of claims 25 to 28 wherein the nucleic acid encodes an antigen.

30. A process according to claim 29 wherein the antigen is selected from the group consisting of viral antigens, bacterial antigens and fungal antigens.

25 31. A process according to any one of claim 25 to 28 wherein the nucleic acid encodes a therapeutic polypeptide.

32. A process according to any one of claims 25 to 31 wherein the nucleic acid is DNA.

30 33. A process according to any one of claims 25 to 32 wherein the nucleic acid condensing agent is a cationic polymer.

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34. A process according to claim 33 wherein the nucleic acid condensing agent is a polyamine.

35. A process according to claim 34 wherein the polyamine is selected from the group consisting of protamines, spermidine, spermine, putrescine and
5 physiologically acceptable salts thereof.

36. A process according to claim 34 wherein the polyamine is a polyarginine or a polysine.

37. A process according to claim 36 wherein the polyarginine is (Arg)₄ or (Arg)₆.

10 38. A process according to any one of claims 25 to 37 wherein the metal ion chelating agent is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA) diethylenetriamine penta-acetic acid (DTPA), nitrilotriacetic acid (NTA), inositol hexaphosphate, tripolyphosphate, polyphosphoric acid, sodium succinate, potassium succinate, lithium succinate, sodium malate, potassium malate,
15 lithium malate, desferal and ethylenediamine-di (o-hydroxy-phenylacetic) acid (EDDHA).

39. A process according to any one of claims 25 to 38 wherein step (i) is further carried out in the presence of one or more disaccharide and/or trisaccharide sugars.

20 40. A process according to claim 39 wherein the one or more sugars is selected from the group consisting of trehalose, sucrose, lactose and raffinose.

41. A process according to claim 40 wherein the one or more sugars is a blend of sucrose and raffinose.

42. A process according to any one of claims 25 to 41 wherein step (i) is
25 further carried out in the presence of one or more salts.

43. A process according to claim 42 wherein the one or more salts is selected from the group consisting of potassium acetate, calcium chloride, lithium chloride, sodium acetate, magnesium nitrate, sodium citrate, sodium phosphate and magnesium chloride.

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44. A process according to any one of claims 25 to 43 wherein the resultant particles from step (i) are contacted with an antioxidant.

45. A process according to claim 44 wherein the antioxidant is selected from the group consisting of ethanol, vitamin A, vitamin C and vitamin E.

5 46. A process according to claim 25 comprising the steps of:

(i) precipitating DNA on inert gold particles in the presence of a polyarginine, EDTA and sucrose; and

(ii) collecting the resultant particles.

47. A method of nucleic acid immunisation comprising

10 (a) providing particles suitable for delivery from a particle-mediated delivery device, which particles are obtainable by precipitating a nucleic acid encoding an antigen on inert metal carrier particles in the presence of a nucleic acid condensing agent and a metal ion chelating agent; and

(b) administering an effective amount of the particles to a subject.

15 48. A method of gene therapy comprising

(a) providing particles suitable for delivery from a particle-mediated delivery device which particles are obtainable by precipitating a nucleic acid encoding a therapeutic polypeptide on inert metal carrier particles in the presence of a nucleic acid condensing agent and a metal ion chelating agent; and
20 (b) administering an effective amount of the particles to a subject .

49. A method according to claim 47 or 48 wherein the inert metal carrier particles are selected from the group consisting of gold, tungsten, platinum and iridium particles.

50. A method according to claim 49 wherein the inert metal carrier
25 particles are gold particles having a diameter from about 1 to 3 μ m .

51. A method according to any one of claims 47 to 50 wherein the nucleic acid is DNA.

52. A method according to any one of claims 47 to 51 wherein the nucleic acid condensing agent is a cationic polymer.

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53. A method according to claim 52 wherein the nucleic acid condensing agent is a polyamine.

54. A method according to claim 53 wherein the polyamine is selected from the group consisting of protamines, spermidine, spermine, putrescine and
5 physiologically acceptable salts thereof.

55. A method according to claim 53 wherein the polyamine is a polyarginine or a polylysine.

56. A method according to claim 55 wherein the polyarginine is (Arg)₄ or (Arg)₆.

10 57. A method according to any one of claims 47 to 56 wherein the metal ion chelating agent is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA) diethylenetriamine penta-acetic acid (DTPA), nitrilotriacetic acid (NTA), inositol hexaphosphate, tripolyphosphate, polyphosphoric acid, sodium succinate, potassium succinate, lithium succinate, sodium malate, potassium malate,
15 lithium malate, desferal and ethylenediamine-di (o-hydroxy-phenylacetic) acid (EDDHA).

58. A method according to any one of claims 47 to 57 wherein precipitation is carried out in the presence of one or more disaccharide and/or trisaccharide sugars.

20 59. A method according to claim 58 wherein the one or more sugars is selected from the group consisting of trehalose, sucrose, lactose and raffinose.

60. A method according to claim 59 wherein the one or more sugars is a blend of sucrose and raffinose.

61. A method according to any one of claims 47 to 60 wherein
25 precipitation is carried out in the presence of one or more salts.

62. A method according to claim 61 wherein the one or more salts, is selected from the group consisting of potassium acetate, calcium chloride, lithium chloride, sodium acetate, magnesium nitrate, sodium citrate, sodium phosphate and magnesium chloride.

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63. A method according to any one of claims 47 to 62 wherein the resultant particles are contacted with an antioxidant.

64. A method according to claim 63 wherein the antioxidant is selected from the group consisting of ethanol, vitamin A, vitamin C and vitamin E.

5 65. A method according to claim 47 comprising the steps of:

(a) providing particles suitable for delivery from a particle-mediated delivery device, which particles have been obtained by precipitating DNA encoding an antigen on gold particles in the presence of a polyarginine, EDTA and sucrose; and

10 (b) administering an effective amount of the particles to a subject.

66. A method according to claim 48 comprising the steps of:

(a) providing particles suitable for delivery from a particle-mediated delivery device, which particles have been obtained by precipitating DNA encoding a therapeutic polypeptide on gold particles in the presence of a polyarginine, EDTA and sucrose; and

15 (b) administering an effective amount of the particles to a subject.

67. Particles, suitable for delivery from a particle mediated delivery device, which comprise inert metal carrier particles having on their surface a nucleic acid, a metal ion chelating agent and one or more of :

20 (i) a nucleic acid condensing agent;

(ii) one or more disaccharide and/or two trisaccharide sugars; and

(iii) one or more salts.